shelden
HEALTHCARE

Dual Combo
User Manual

Specialist Suppliers to the Healthcare Industry

Thank you for purchasing this Shelden Healthcare pressure relieving mattress system.

PLEASE READ THIS USER MANUAL CAREFULLY BEFORE SETTING UP AND USING THE DEVICE.

Pay special attention to the warnings and other safety information. Use genuine Shelden Healthcare components to maintain the products optimal performance. If you do not fully understand all the instructions, safety precautions, and warnings, do not use this device. In case you have questions, please contact Shelden Healthcare on 01788 833 989.

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1.0 Indications

Attention! Please read enclosed document thoroughly

Declaration of Conformity to Medical Device Directive (93/42/EEC)

Disposal of Electrical & Electronic Equipment (WEEE):

This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

"BF" symbol, indicate this product is according to the degree of protecting against electric shock for type BF equipment.

Indications

This alternating pressure seat cushion system is designed for patients who are at high risk of pressure of ulcers or require treatment for existing pressure ulcers. This device is intended to treat and prevent pressure ulcers by facilitating blood circulation, reactive hyperaemia and decreasing interface pressures. Always consult a physician or health professional before using this mattress system. This pressure relieving mattress system is suitable for patients assessed to be high risk and up to catagory 3 pressure ulcers.

Contraindications

Certain patient conditions are not suitable for using this type of device. Contraindications such as unstable fractures of vertebrae and conditions of the vertebrae. Always consult a physician or health professional before using this device.

The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient.

Danger

(1) Always unplug this product immediately after using.

(2) Do not use while bathing.

(3) Do not place or store this product where it can fall or be pulled into a tub or sink.

(4) Do not place in or drop into water or other liquid.

(5) Do not reach for a product that has fallen into water. Unplug immediately.

Warnings

(1) This product should never be left unattended when plugged in.

(2) Close supervision is necessary when this product is used by, on, or near children or invalids.

(3) Use this product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer

(4) Never operate this product if it has a damaged cord or plug, if it is not working properly, or if it has been dropped, damaged, or dropped into water. Return the product to a service center for examination and repair.

(5) Keep the cord away from heated surfaces.

(6) Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where their openings may be blocked. Keep the air openings free of lint, hairs, and other similar particles.

7) Never drop or insert any object into any opening or hose of this product.

NOTE: Indicate some tips.

CAUTION: Indicate correct operating or maintenance procedures in order to prevent damage to or

destruction of the equipment or other property

WARNING: Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

2.0 Introduction

This manual should be used for initial set up of the system and for reference purposes.

2.1 General Information

Combo 100 is a high quality and affordable pressure relief seat cushion system for wheelchair users. It helps to decrease the concentrated pressure, distribute the pressure over the entire contacted interface and stimulate capillary blood flow for pressure ulcer prevention.

The system has been tested and successfully approved to the following standards:

CE

EN 60601-1
EN 60601-1-2

2.2 Intended Use

The product is intended to help and reduce the incidence of pressure ulcers while optimizing patient comfort. It also provides following purposes:

I. Individual home care setting and long term care of people who are under risk of pressure ulcer II. Pain management as prescribed by a physician for ulcer stage development

NOTE: The pump has no AP or APG protection.

NOTE: Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

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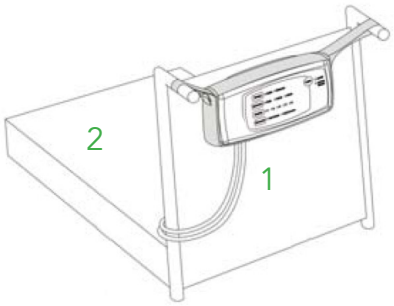


Standard Parts	
Pump unit	1 PCS
Seat Cushion	1 PCS
Carry Bag	1 PCS
User Manual	1 PCS
Accessory Parts	
Power Adaptors	1 PCS(DC 12V output , universal power input)
Battery Pack	1 PCS(6V) (NEXcell, AAx5)

CAUTION:

1. Do not drop water on to the device.

2. Do not apply shock to the device.

3. Do not disassemble or modify the device.

4. Do not obstruct the air outlet.

5. Do not use the power adapter and battery pack not provided by the manufacturer.

6. To prevent battery pack damage, please remove the battery pack from the battery compartment when not using the device for a long period.

3.0 Product Description

Combo 100 is an active alternating pressure seat cushion system and consists of a reliable pump and seat cushion providing the best pressure relief. It equips with a fully digitalized pump and each function mode can be adjusted individually, such as cycle time and comfort range. It provides you the total pressure management control and runs on AC power supply or a Ni-MH rechargeable battery.

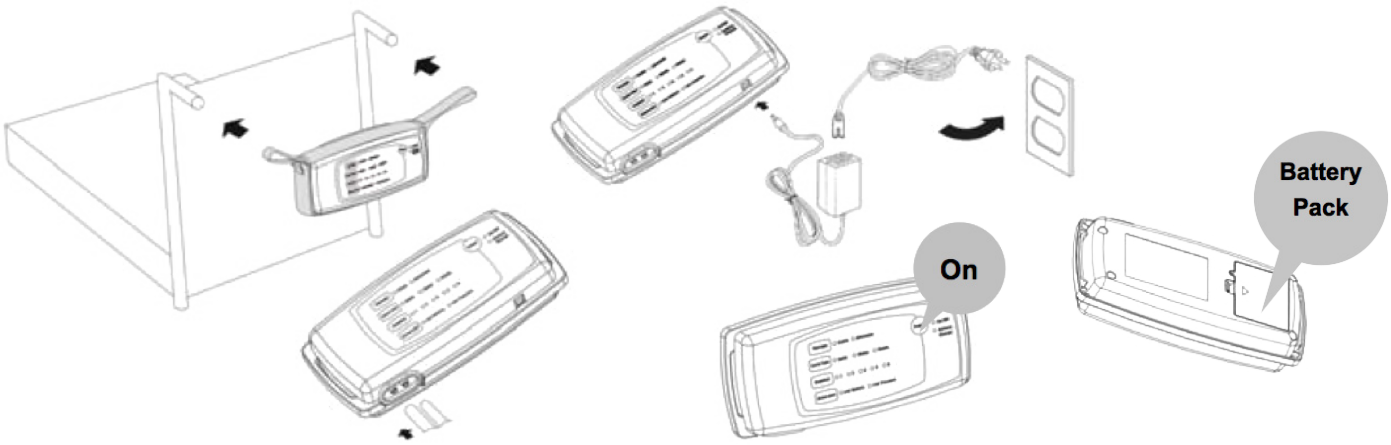
3.1 Pump (9P-048 series) and Seat Cushion System

The Parts of Combo100 is listed as below table.

1. Pump Unit
2. Cushion
3. Control Panel
4. Adaptor Outlet
5. Air Hose Port

4.0 Installation

Unpacking the box to remove the pump unit, seat cushion and other accessories and check for any damage, which may have occurred during shipping. If there is any damage, please contact your dealer immediately.



4.1 Setting Up

(1) Place the seat cushion on top of the (wheel) chair. The slip-resistance mat found at the bottom of cushion will prevent any slippery.

(2) Put on the carry bag for the pump and hang the pump onto the (wheel) chair's handle or frame with the straps of the carry bag.

(3) Connect air hose from the seat cushion to the pump unit.

NOTE: Check and ensure the air tubes are not kinked or tucked under the cushion.

(4) Plug into mains electrical outlet.

NOTE: When using battery as the power source, be sure that the battery pack is put in the compartment and it is fully charged. The unit's main power source will switch to the battery pack only when the adaptor is disconnected from the outlet.

NOTE:The plug is also served to disconnect the device.

CAUTION:The pump can only be applied to the air seat cushion recommended by the manufacturer. Do not use it for any other purpose.

(5) Press the power button to start the machine. When the pump unit is turned on, the ON/OFF indicator will light.

(6) Battery Pack instruction:

- Please make sure the battery is fully charged (the battery charge indicator stop lighting up). The suggested charging time is 17 hours for the first time. The typical charging period is 12-14 hrs for daily use.

- When AC power cord is not connected, the unit's main power source is from the rechargeable Ni-MH battery pack. Note that even when the pump is turned off, it is still in the stand-by condition and consuming the battery power. It usually takes takes three days to use up the battery power if pump is not actuated after the battery pack is fully charged. It is suggested that users charge the battery pack fully at night and use the pump during the next day.

- When the power in the battery pack becomes low, the low battery indicator flashes to indicate that only a few minutes of battery power remains. You must recharge battery pack or use AC power source.

CAUTION: If the charging time is over 24 hrs but the battery charge indicator still lights up, please do NOT continue to charge the battery but disconnect the adapter for safety consideration.

4.2 Battery Status Indicator

Regularly check the battery indicator on the control panel to determine the status of the rechargeable battery. The following indicators indicate the battery status:

- Low Battery indicator light: Low Battery

- Battery Charge indicator light: AC power is charging the battery.

NOTE: Although the battery pack can be charged when pump is in operation by using the adapter, it may not be fully charged when battery charge indicator light turns off. It is recommended that users turn off the pump to fully charge the battery.

CAUTION:

(1) Please keep out the reach of the children to the battery pack.

(2) The battery pack is Ni-MH rechargeable battery, which can explode if not properly replaced,

used, handled or disposed.

(3) Dispose of the battery as required by local ordinances or regulations.

5.0 Operation

NOTE: Always read the operating instruction before use.

Control Button & Indication	Function Description
Power	To turn on control unit.
Alarm Mute	Enable and disable the audible alarm feature. Press this button to silent the audible alarm.
Therapy	To switch the therapy mode: alternating or static mode.
Cycle Time	To adjust the pressure alternating cycle time to 5 min, 10 min, or 15 min
Comfort	To adjust the comfort level according to user's preference or physician's suggestion. There are 5 different comfort levels and 1 is the softest & 5 is the firmest. The default setting is at comfort level 1.
Low Battery Indicator	To indicate the battery power is low
Low Pressure Indicator	To indicate that the pressure of seat cushion drops below a half of comfort setting
Battery Charge Indicator	To indicate the internal rechargeable battery pack is under charge

5.1 Operating Instruction

(1) Press the POWER button on the display panel to start the system.

(2) Before cushion is fully inflated, user can change the comfort setting according to their preference or physician's recommendations.

5.2 Comfort Range and Operation Mode Setup

Users can adjust the comfort range according to their preference or physician's suggestion. At startup and every setup, the low pressure indicator will always light up. It means the preset pressure has not been reached. The indicator will light off after the system reached to the desired pressure.

The unit provides two operation modes for option, alternating and static pressure mode. Please select the correct settings. The pressure alternating cycle time is also adjustable 5 minutes, 10 minutes or 15 minutes.

5.3 Low Pressure

When an abnormal low pressure condition occurs, the Low Pressure indicator will firstly light up and flash. If the low pressure condition is not solved in 30 seconds, the pump will initiate the audible alarm. It might be caused by loose connection of air tubing. Check all connections are securely and correctly made. Make sure that they are correctly installed per installation instructions.

Examine if there are any air leakages between pump and the cushion connections or from air tubing of the cushion.

Check connectors between air cushion and pump. If they are disconnected, please reconnect securely.

1. Check each air cell. Please select the operation mode as static mode so that all the air cells will be inflated. Then ensure each single cell is not broken.

2. Exam air leakage from tubes. Ensure no leakage occurs. If any leakage occurs, please contact your vender.

3. Plug in the pump unit and check the airflow from the hose connection port. The airflow should alternate between ports every half-cycle time.

NOTE: If the pressure level is consistently low, check if any leakage (tubes or connecting hoses), If necessary, replace any damaged tubes or hoses, or contact Shelden Healthcare.

NOTE: Sometimes the Low Pressure indicator will light upand flash temporarily when users leave the cushion. It's a normal condition for inner pressure of the bladder suddenly changes when cushion is unloaded.

To mute the alarm, simply press the alarm mute button; however, the Low Pressure indicator still remains on. In addition, the alarm will re-start in 3 minutes if the pump is still under the low pressure condition after pressing the alarm mute button.

6.0 Cleaning

In this section describes the procedures to clean the system. It is important to follow these procedures and thoroughly clean a used system. It will greatly help to prevent patients and/or doctors from the possibility of getting infection.

6.1 Pump Unit

Wipe with a damp cloth and a mild detergent and keep it away from dust. If other detergent is used, choose one that will have no chemical effects on the surface of the plastic case of the pump unit. All parts should be air dried thoroughly before use.

CAUTION: Ensure the pump unit is disconnected from the mains before cleaning.

6.2 Air Seat Cushion

CAUTION: Do not use phenolic based products for cleaning. Please ask your distributor for suitable and locally available cleaner.

The carrying bag (if available) should be turned inside out and completely wiped down using the disinfectant solutions. Allow it to air-dry thoroughly. Once the inside is dry, turn it back and wipe down the outside of the bag with disinfectant solutions.

CAUTION: Dry the SeatCushion on SUNLESS capitalized area after cleaning.

7.0 Storage

(1) Disconnect the air hose from the cushion to the pump and make sure all cells are deflated.

(2) Lay the seat cushion out flat and upsides down.

(3) Protect the air tube coupler by putting it in the inner side of seat cushion.

(4) Take away the Ni-MH battery pack from the pump and make sure the battery fully charged every 3 months. This will help to keep the performance and life of the battery.

8.0 Maintenance

(1) Check main power cord and plug if there are any abrasions or excessive wears.

(2) Check the covers of seat cushion for signs of wear or damage. Ensure tubings are stubbed together correctly.

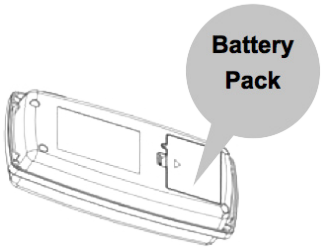
(3) Check the air hoses if there is kinked or broken. For replacement, please contact local distributors.

(4) Check the pump unit and make sure both the power and the power indicator are off when the switch is turned off.

8.1 Battery Pack Replacement

If the low battery indicator still light up after it's fully recharged (12-14 hrs), it indicates the battery pack might need to be replaced (about 500 recharges).

CAUTION: It is prohibited to use the battery pack not from Shelden Healthcare. The charging function of the pump is designed for the battery pack only. Any damage by other battery pack not supplied by Shelden Healthcare will not be warranted.



To replace the battery pack, follow the instructions below.

(1) Remove the AC power source.

(2) Open the battery cover on the back of the pump unit.

(3) Release the electrical connector and take the battery out of its compartment.

(4) Replace a new battery pack and connect the electrical connector and put the cover back on. Battery packis available from yourv ender.

NOTE: Higher temperature will shorten life of the battery pack, please keep the battery in a cold condition and avoid direct sunlight.

9.0 Troubleshooting

Problem	Solution
Power is NOT on.	Check if the plug is connected to mains. Check if the power cord is well connected to the pump
Alarm is ON (audible & visual)	Check if the connection between air tube connector to pump unit is tightly secured. Check if all tubing connections along cushion are secured. Check if there is any leakage on air cells. Check if the battery is low
Cushion becomes too firm and pressure can't be lower down	The pressure is too firm for too long, release some air by disconnecting the air tube connector and change to your preferred setting.
No air is produced from some air outlet of the air tube connector	This is normal since it is at alternating mode. Air outlets take turn to produce air during their preset cycle time.

10.0 Technical Specifications

Item		Specification
Model		9P-048 series
Power Source		DC12V, 2.5 A by Adaptor
Power consumption		12V DC, 850mA
Device Dimension (L x W x H)		25cm x 12.5cm x 5.5 cm or 9.8" x 4.9" x 2.2"
Device Weight		960g or 2.1lb (battery and adaptor included)
Environment	Temperature	Operation: 0°C to 40°C (32°F to 104°F) Storage: -10°C to 50°C (14°F to 122°F) Shipping: -10°C to 70°C (14°F to 158°F)
	Humidity	Operation: 30% to 75% non-condensing Storage: 10% to 75% non-condensing Shipping: 10% to 90% non-condensing
Classification		Type BF, IPX0
		Applied part: Air Seat Cushion Not suitable for use in the presence of a flammable anesthetic mixture (No AP or APG protection)
Pressure Range		40mmHg – 100 mmHg
Battery Pack		6V Ni-MH Battery (2300mAh typical) (recommended type NEXcell , AAx5)
Cushion		Specification
Dimension (L x W x H)		17" x 17" x 4"
Weight		1.44 kg or 3.2lb

If your questions can't be answered with above information, please contact Shelden Healthcare. They might require a technician to take care the problem.

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